

510(k) Summary of Safety and Effectiveness**Name, Address
and
Establishment
Registration
No.**

The address and registration number of the manufacturer is as follows:

Hand Innovations, LLC

8905 SW 87 Avenue, Suite 220

Miami, FL 33176-2227

Establishment Registration No.: 9042874

Tel.: (305) 270-6899

Fax: (305) 412-8060

APR 28 2005

**General
Provisions**

The name of the device is:

Proprietary Name	Common or Usual Name
Multidirectional Threaded Peg	Plate Fixation Bone

**Name of
Predicate
Devices**

The device is substantially equivalent to:

- Threaded Peg of the Distal Volar Radius Anatomical Plate System (510(k) # K050932 – April 26, 2005) – Hand Innovations, LLC.

Classification

Class II.

**Performance
Standards**

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

**Indications for
Use**

The Multidirectional Threaded Pegs have the same indications for use as the predicate device:

The Distal Volar Radius Anatomical Plate System is intended for the fixation of fractures and osteotomies involving the distal radius.

**Device
Description**

The proposed **Multidirectional Threaded Peg** is manufactured from Cobalt Chromium (CoCr) and is available in 2.5 mm diameter and in a variety of lengths, ranging from 10 – 30 mm in 2 mm increments to accommodate varying patient anatomies and fracture morphologies.

**Biocompati-
bility**

The Proposed **Multidirectional Threaded Peg** do not require biocompatibility testing because the CoCr Alloy used in the fabrication meets the requirements of ASTM F 1537-00.

**Summary of
Substantial
Equivalence**

The proposed **Multidirectional Threaded Peg** is substantially equivalent to the predicate threaded peg of the Distal Volar Radius Anatomical Plate System. The equivalence was confirmed through pre-clinical testing.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2006

Hand Innovations
c/o Ms. Natalie S. Heck
Manager, Regulatory Affairs
DePuy Orthopaedics, Inc.
8905 SW 87th Avenue, Suite 220
Miami, Florida 33176

Re: K060864
Trade/Device Name: Multidirectional Threaded Peg
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Codes: LXT
Dated: April 24, 2006
Received: April 26, 2006

Dear Ms. Heck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

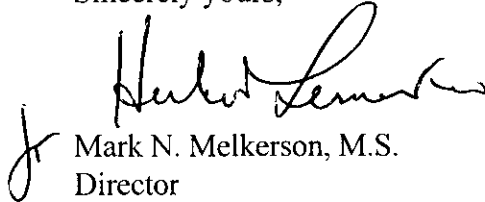
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a large initial "M".

Mark N. Melkerson, M.S.

Director

Division of General, Restorative and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K060864

Device Name: **Multidirectional Threaded Peg**

Indications for Use Statement

The Distal Volar Radius Anatomical Plate System is intended for the fixation of fractures and osteotomies involving the distal radius.

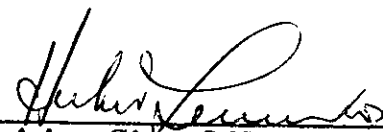
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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

OR

Over-The-Counter Use _____


(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K060864